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UNCLAS SECTION 01 OF 03 TAIPEI 002498

SIPDIS

C O R R E C T E D C O P Y (ADD SENSITIVE CAPTION)

STATE PLEASE PASS TO AIT/W AND EAP/RSP/TC

STATE PASS USTR/DAVID KATZ AND CHRIS WILSON

USDOC FOR 4430/ITA/MAC

SIPDIS

SENSITIVE

E.O. 12958: N/A
TAGS: ETRD ECON KIPR TW
SUBJECT: Taiwan Pharma: Patent Linkage Going Nowhere

Reftel: Taipei 1788

Summary

¶1. (SBU) Taiwan lacks a patent-linkage notification requirement and allows generic-drug licensing before patent expiry, practices that foreign pharmaceutical manufacturers claim allow local generic drug makers to infringe on patent-holders' rights and, in some cases, result in the Bureau of National Health Insurance (BNHI) reimbursing pharmacies at an unfairly-high rate for generic drugs. The U.S. and the Taipei American Chamber of Commerce have pushed the Taiwan authorities to implement a U.S.-style patent-linkage system that would continue to allow generic-drug testing before the original drug's patent expiration, but would define a time period before which generic-drug manufacturers cannot use patented data for research or production trials; would enforce a "data-exclusivity" period before which generics cannot use safety and efficacy data provided by patent-holders to regulatory agencies; would require generic-drug manufacturers to notify patent-holders before using the patent-holder's intellectual property for research or trials; and would prevent generic-drug makers from licensing a generic form of a patented drug and getting a reimbursement price while the original patent is still valid. However, the authorities responsible for drafting amendments to Taiwan's laws to implement patent linkage do not see a need for such a system in Taiwan and believe that the Taiwan judicial system is adequate for protecting original-drug manufacturers' IPR. Therefore, progress toward this reform would require sustained U.S. engagement with Taiwan authorities. End summary.

Patent Linkage: What is it?

¶2. (U) Patent linkage is a regulatory system whereby patent-holders register pharmaceutical patents with a responsible agency that--after a set period has passed--allows generic makers to use the patented information for research and clinical trials as long as the generic-drug maker notifies the patent-holder. Patent-linkage systems also protect--again for a set period of time--the safety and efficacy data that original-drug manufacturers provide to regulators when the new drug is being considered for approval, the so-called "data-exclusivity" period. Under a patent-linkage system, the

responsible agency will not allow a generic-drug maker to begin marketing or selling a knock-off drug until the original patent and data-exclusivity period have both expired, or a responsible government body rules that the patents have not been infringed upon or are invalid.

¶3. (U) In the United States, the responsible agency is the Food and Drug Administration (FDA), which, in consultation with the Patent and Trade Office (USPTO), compiles pharmaceutical patents and information on the patent-holders in its "Orange Book." When a generic manufacturer begins research or clinical trials using drugs or processes that have been patented in the United States and included in the Orange Book, U.S. law requires the manufacturer to notify the patent-holder. This notification system allows patent-holders to ensure that generic makers are respecting intellectual property rights and do not use patented information to bring a knock-off drug to market before the original patent and data-exclusivity periods expire.

How Would Taiwan Implement It?

¶4. (U) If Taiwan wanted to adopt a U.S.-style patent-linkage system for protecting pharmaceutical patents, the Taiwan Intellectual Property Office (TIPO) would submit an amendment to Patent Act Article 57 to the Executive Yuan for approval and submission to the Legislative Yuan, and the Department of Health (DOH) would do the same to Article 40 of the Pharmaceutical Affairs Law. The amendments would allow companies intending to register a generic version of a drug with BNHI to use the patented information to conduct research and trials, but would not allow the generic maker to register the knock-off drug before the expiry of the original drug's patent term without the patent holder's consent. The amendment would also designate an official "competent authority" with oversight of the patent-linkage system to notify the patent-holder and holder of the license for the original drug of the same ingredients, so that they would be able to monitor any potential violations of their patent or license.

Why Does Taiwan Need It?

¶5. (U) Taiwan does not have an original-drug industry, and foreign drug-makers claim that Taiwan's pharmaceutical laws often favor the island's large off-patent drug-manufacturing sector. For example, although Taiwan law does not allow pharmaceutical companies to sell a generic drug until the original drug's patent has expired, the DOH does allow generic makers to use patented information to produce drugs for clinical trials and other pre-production research and then apply for a license for the generic before the expiration of the original drug's patents. With the license, the knock-off manufacturer can then apply for a reimbursement price from the Bureau of National Health Insurance (BNHI), a price that will not be re-evaluated by subsequent BNHI price-volume surveys (PVS) until after the drug comes onto the market.

¶6. (SBU) Original manufacturers claim that this often gives a generic manufacturer an unfairly high price vis-a-vis the original drug during the time between the expiry of the original patent and the subsequent price-reduction on the generic drug by the next BNHI drug price-volume survey (PVS). [Please see reftel for an overview of the PVS system. End note.] For example, the patent for the Pfizer product Lipitor will not expire until 2016, but one generic manufacturer has already secured a production license and BNHI reimbursement price on a knock-off version. In another case, before the patent on Pfizer's anti-hypertension drug Norvasc expired in March 2007, 17 local generic-drug manufacturers had--unknown to Pfizer--already used the company's IPR to produce, register, and receive BNHI prices for generic versions. A U.S.-style patent-linkage system would not allow a generic to be licensed until the original drug's patent expires, thus eliminating this "loophole" in Taiwan's current drug-pricing system.

¶7. (SBU) Patent linkage would also benefit original-drug

manufacturers by ensuring that generic-drug manufacturers automatically notify original makers as the generic makers start research on and begin filing applications for marketing authorization of a knock-off drug. Foreign makers claim that the current lack of such notification allows local manufacturers to use patented information to research, produce, and, in some cases, bring to market drugs that are based on an original makers' intellectual property, all without the patent-holder's consent or knowledge. In addition to the Pfizer case above, original-drug manufacturers point to several ongoing legal cases in which BNHI mistakenly allowed a generic drug to come to market before the patent it was based on expired. The patent on the Bristol-Myers Squibb (BMS) drug Plavix will expire in 2018, but BMS claims that three generics that use the company's intellectual property are already on the market. [Note: Plavix's patent-holder is a French company, but BMS has a license to produce it in Taiwan. End note.] Eli Lilly claims that Taiwan's Tungyang Chemical Industries Company illegally used an Eli Lilly process patent to bring a drug to market in 2003, and has been fighting an expensive legal battle with Tungyang in the Taiwan courts for over four years.

¶8. (SBU) These U.S. companies told us that a U.S.-style patent-linkage system would have notified them of these IPR infringements early enough to take action against the local companies, and would also have prevented the generics from reaching the market until after the expiry of the original patents. Although these companies are not able to estimate for us how much Taiwan's lack of such a system has cost them, the International Research-based Pharmaceutical Manufactures Association (IRPMA), foreign drug-makers' industry group in Taiwan, recently asked its members to calculate the number of each member company's drugs that would have benefited from having patent linkage in Taiwan, as well as the estimated losses each company has suffered as a result.

BOPA, TIPO, BNHI Don't Want to Bother

¶9. (SBU) Econoff met recently with Dr. Chi-chou Liao BOPA's Director General for Pharmaceutical Affairs, to discuss BOPA's view of patent linkage. Dr. Liao believes that a U.S.-style patent-linkage would be overly-complicated and would require a high level of patent knowledge on the part of the Taiwan authorities that the island simply doesn't have. Dr. Liao told us that BOPA is also concerned that BOPA would face lawsuits for any mistakes or misconduct that the Bureau or its officials might make in compiling an Orange Book, going through notification procedures, or ensuring enforcement of the patent-linkage mechanism.

¶10. (SBU) Dr. Liao told econoff that instead of creating such a complicated system to enhance IPR protection, Taiwan would be better off simply ensuring that Taiwan's Intellectual Property (IP) Court--which will begin hearing cases in July 2008--has prosecutors and judges with enough pharmaceutical expertise to properly handle

patent-infringement disputes using current Taiwan laws. [Note: On November 9, econoff talked briefly with two local, U.S.-trained lawyers who recently completed a report to BOPA on patent-linkage systems used outside of Taiwan. While the two would not reveal the report's conclusions, they hinted that the report does not recommend that Taiwan adopt a patent-linkage system due to its complexity. End note.]

¶11. (SBU) TIPO's Secretary General, Margaret Chen, recently told econoff that her organization does not want to create an "Orange Book" of pharmaceutical patents. She said that although TIPO would assist in compiling such a patent book if directed by the EY, the Office is not considering this move and does not think that Taiwan needs a patent-linkage system. TIPO echoed BOPA's belief that the Taiwan judicial system is adequate for protecting original-drug manufacturers' IPR.

¶12. (SBU) Cheng-hua Lee, Vice President and CIO of Taiwan's Bureau of National Health Insurance (BNHI), recently told econoff that BNHI, too, does not see the need for a patent-linkage system in Taiwan. He echoed Dr. Liao's belief that implementing patent linkage

would require too high a level of patent knowledge on the part of the Taiwan authorities. He added that only one current patent dispute case in Taiwan would have benefited from the protections of a U.S.-style patent-linkage system, and that BNHI's actions to alert hospitals and pharmacies of the resulting patent-dispute case is adequate to protect the original manufacturer's property rights pending a ruling from Taiwan's court system on the case.

Comment

¶13. (SBU) BOPA, BNHI, and TIPO are the three offices in Taiwan responsible for implementing pharmaceutical-related policy, and none of the three supports the creation of a patent-linkage system as advocated by foreign original-drug manufacturers. Therefore, progress toward this reform would require sustained U.S. engagement with Taiwan authorities. We may want to emphasize to the Taiwan authorities that a patent-linkage system would help local companies understand an original patent's status before starting an expensive drug-development program; would ensure that Taiwan's regulatory agencies have the right information to fairly evaluate patent use; would save judicial resources of the new Intellectual Property Court by minimizing lengthy and complex patent disputes; and would help foster a stable and legally-friendly environment for international drug manufacturers as they consider both where to introduce new products and where to spend their drug-development dollars. End comment.